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|--|---------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/550,516   | 05/26/2006    | Staffan Stromblad    | P07900US01/BAS      | 4509             |
| 881  | 7590          | 12/04/2007           | EXAMINER            |                  |
| STITES & HARBISON PLLC<br>1199 NORTH FAIRFAX STREET<br>SUITE 900<br>ALEXANDRIA, VA 22314 |               |                      | PACKARD, BENJAMIN J |                  |
| ART UNIT   | PAPER NUMBER  |                      |                     |                  |
|  |               | 4173                 |                     |                  |
| MAIL DATE  | DELIVERY MODE |                      |                     |                  |
| 12/04/2007   | PAPER         |                      |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |   |
|------------------------------|--|---|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/550,516   | <b>Applicant(s)</b><br>STROMBLAD ET AL. |
|                              | <b>Examiner</b><br>Benjamin J. Packard | <b>Art Unit</b><br>4173                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 October 2007.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) 1, 2, and 6-11 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 3-5 is/are rejected.

7) Claim(s) 5 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/0256/06)  
Paper No(s)/Mail Date (1 sheet).

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

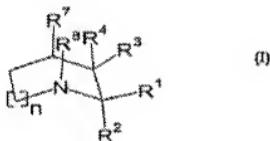
5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Group I, including claim 5 and amended claims 3-4, further electing the species wherein:



n is 1;

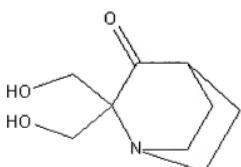
R<sup>1</sup> and R<sup>2</sup> are both -CH<sub>2</sub>-O-R<sup>5</sup>;

R<sup>3</sup> and R<sup>4</sup> are together = O;

R<sup>5</sup> is H; and

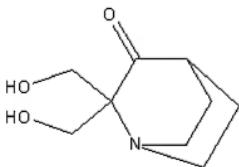
R<sup>7</sup> and R<sup>8</sup> form together a bridging CH<sub>2</sub>-CH<sub>2</sub> moiety, in claim 5.

in the reply filed on 10/29/2007 is acknowledged. Note, the structure in the specification at page 18 is defined as 2,2-bis(hydroxymethyl)-1-azabicyclo[2.2.2]octan-3-one has the structure:



2,2-bis(hydroxymethyl)-1-azabicyclo[2.2.2]octan-3-one

can also be defined as 2,2-bis(hydroxymethyl)quinuclidin-3-one with the same structure as follows:



2,2-bis(hydroxymethyl)quinuclidin-3-one

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction is made FINAL.

Claims 1-2 and 6-11 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 3-5 are now examined.

### ***Claim Objections***

**Claim 5** is objected to because of the following informalities: a space is missing between the following words: "and" and "-CH2-O-CO-NHR5"; "together" and "=CH2"; "from" and "-H"; and "pr" and "=NHR5". Also, when referring to C1 (i.e., one carbon), Applicants use "C1" throughout the claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 3-5** are rejected under 35 U.S.C. 103(a) as being obvious over BYKOV, et al (WO/2002/024692), in view of Hartmann et al (Overexpression And Mutations Of P53 In Metastatic Malignant Melanomas, *Int. J. Cancer*: 67,313-317 (1996)).

BYKOV et al teaches 2,2-bis(hydroxymethyl)quinuclidin-3-one (claim 2) for the treatment of human tumors (page 12 lines 3-5) by reactivating the apoptosis-inducing function of p53 (page 11, lines 1-6) where the compound is the same as the elected compound (see Election/Restrictions section above). Further, the compound may be used in pharmaceutical compositions (page 11, lines 10-13). BYKOV et al does not specifically disclose treatment of malignant melanoma.

Hartmann et al teaches inactivated p53 is present in malignant melanoma cells (see page 315, discussion).

One skilled in the art would find it obvious to apply the teaching of BYKOV et al to use 2,2-bis(hydroxymethyl)quinuclidin-3-one to treat human tumors which contain inactivated p53, including malignant melanoma as taught by Hartmann et al. Applying these teachings, one skilled in the art would find the instantly claimed method obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 3-5** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,921,765, in view of Hartmann et al (cited above).

US Patent No. 6,921,765 claims the treatment of "cancer", whereas the current application claims treatment of "malignant melanoma". Hartmann et al teaches malignant melanoma is a form of cancer (see page 316). One skilled in the art would find it obvious to apply the cancer treatment method of US 6,921.765 to specific cancers, such as malignant melanoma.

**Claims 3-5** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/590,054 in view of Hartmann et al (cited above).

Claims 1-2 of copending Application No. 10/590,054 claim the treatment of "cancer", whereas the current application claims treatment of "malignant melanoma". Hartmann et al teaches malignant melanoma is a form of cancer (see page 316). One skilled in the art would find it obvious to apply the cancer treatment method of copending Application No. 10/590,054 to specific cancers, such as malignant melanoma.

This is a provisional obviousness-type double patenting rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 9-4:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

26 November 2007  
BP

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614